

REMARKS/ARGUMENTS

The election/restriction requirement dated March 23, 2007 has been considered. The Applicant hereby elects the claims of Invention I (claims 1-7) and respectfully traverses the restrictions of the Office Action mailed on March 23, 2007 (hereinafter Office Action).

While not acquiescing to the Examiner's distinctions between claims 1-7, identified by the Examiner as Invention I; claims 8-22, identified by the Examiner as Invention II; claims 23-37, identified by the Examiner as Invention III; claims 38-41, identified by the Examiner as Invention IV; claims 42-48, identified by the Examiner as Invention V; claims 49-54, identified by the Examiner as Invention VI; and claims 58-62, identified by the Examiner as Invention VIII; the Applicant will use this convention for convenience in addressing the restriction herein.

The restrictions between Inventions II and I; III and II, IV and I; VII and I; II and III; II and IV; II and VII; III and IV; III and VII and VI; V and VII; and VI and VII are based on subcombinations disclosed as usable together. Restriction of subcombinations is only proper if the subcombination can be shown to have utility either by itself or in another materially different combination. MPEP § 806.05(d)(B).

In regard to the restriction between Inventions I and II, the Examiner states that Invention II has separate utility such as storage of the cardiac signals for later review and diagnosis by a physician. (Office Action, Page 3). The Applicant respectfully submits that Invention I includes memory (see claim 3) and a transmitter for transmitting the contents of the memory to a patient-external device (see claim 6). Accordingly, Invention I has the utility that was contended to be found in Invention II but absent from Invention I.

In regard to the restriction between Inventions III and I, the Examiner states that Invention III has separate utility such as a patient controlled method of operating the implantable device, for example by actuating a switch to transition the cardiac device between the two modes of operation. (Office Action, Page 3) The Applicant respectfully submits that Invention I includes a mode switch to transition the cardiac device between two modes of operation (see claim 5). Accordingly, Invention I has the utility that was contended to be found in Invention III but absent from Invention I.

In regard to the restriction between Inventions IV and I, the Examiner states that Invention IV has separate utility such as external storage of cardiac signals for review by a physician that is remote from the patient. (Office Action, Page 4). The Applicant respectfully submits that Invention I includes a transmitter for transmitting the contents of the memory to a patient-external device (see claim 6). Accordingly, Invention I has the utility that was contended to be found in Invention IV but absent from Invention I.

In regard to the restriction between Inventions VII and I, the Examiner states that Invention VII has separate utility such as external storage of cardiac signals for review by a physician that is remote from the patient. (Office Action, Page 4). The Applicant respectfully submits that Invention I includes a transmitter for transmitting the contents of the memory to a patient-external device (see claim 6). Accordingly, Invention I has the utility that was contended to be found in Invention VII but absent from Invention I.

In regard to the restriction between Inventions II and IV, the Examiner states that Invention IV has separate utility such as external storage of cardiac signals for review by a physician that is remote from the patient. (Office Action, Page 5). The Applicant respectfully submits that Invention II includes a transmitter for transmitting the contents of the memory to a patient-external device (see claim 11). Accordingly, Invention II has the utility that was contended to be found in Invention IV but absent from Invention II.

In regard to the restriction between Inventions II and VII, the Examiner states that Invention VII has separate utility such as external storage of cardiac signals for review by a physician that is remote from the patient. (Office Action, Page 6). The Applicant respectfully submits that Invention II includes a transmitter for transmitting the contents of the memory to a patient-external device (see claim 11). Accordingly, Invention II has the utility that was contended to be found in Invention VII but absent from Invention II.

In regard to the restriction between Inventions III and IV, the Examiner states that Invention IV has separate utility such as external storage of cardiac signals for review by a physician that is remote from the patient. (Office Action, Page 6). The Applicant respectfully submits that Invention III includes a transmitter for transmitting the contents of the memory to a patient-external device (see claim 36). Accordingly, Invention III has the utility that was contended to be found in Invention IV but absent from Invention III.

In regard to the restriction between Inventions III and VII, the Examiner states that Invention VII has separate utility such as external storage of cardiac signals for review by a physician that is remote from the patient. (Office Action, Page 7). The Applicant respectfully submits that Invention III includes a transmitter for transmitting the contents of the memory to a patient-external device (see claim 36). Accordingly, Invention III has the utility that was contended to be found in Invention VII but absent from Invention III.

In regard to the restriction between Inventions IV and VII, the Examiner states that the subcombination has separate utility such as distinguishing between different types of cardiac arrhythmia for patient diagnosis. (Office Action, Page 8). The Applicant respectfully submits that it is unclear how the subcombination has the utility of distinguishing between different types of cardiac arrhythmia for patient diagnosis while the combination does not. For example, both Inventions include detection circuitry or monitoring means, and neither recites distinguishing between different types of cardiac arrhythmia for patient diagnosis. Clarification is requested.

In regard to the restriction between Inventions V and VI, the Examiner states that Invention VI has separate utility such as storing sensed cardiac data for later physician diagnosis and review. (Office Action, Page 8). The Applicant respectfully submits that Invention V includes cardiac event storage (see claim 43). Accordingly, Invention V has the utility that was contended to be found in Invention VI but absent from Invention V.

In regard to the restriction between Inventions V and VII, the Examiner states that Invention VII has separate utility such as external storage of cardiac signals for review by a physician that is remote from the patient. (Office Action, Page 9). The Applicant respectfully submits that Invention V includes cardiac event storage (see claim 43). Accordingly, Invention V has the utility that was contended to be found in Invention VII but absent from Invention V.

In regard to the restriction between Inventions VI and VII, the Examiner states that Invention VII has separate utility such as external storage of cardiac signals for review by a physician that is remote from the patient. (Office Action, Page 9). The Applicant respectfully submits that Invention VI includes memory for storing cardiac event data (see claim 49), diagnosis (see claim 52), and transmitting the stored cardiac event data to a

patient-external device (see claim 53). Accordingly, Invention VI has the utility that was contended to be found in Invention VII but absent from Invention VI.

Therefore, the Examiner has failed to meet the requisite burden to establish that subcombinations of Inventions II and I; III and II, IV and I; VII and I; II and III; II and IV; II and VII; III and IV; III and VII and VI; V and VII; and VI and VII have separate utility and are properly restrictable. (MPEP § 806.05(d)(B)). For at least these reasons, the Applicant respectfully requests withdrawal of the restriction between Inventions II and I; III and II, IV and I; VII and I; II and III; II and IV; II and VII; III and IV; III and VII and VI; V and VII; and VI and VII.

Restriction between inventions related as a process and apparatus requires that “the process *as claimed* can be practiced by another materially different apparatus”. (806.05(e)(A); emphasis original). The MPEP further states that “[t]he burden is on the examiner to provide reasonable examples that recite material differences.” (Id.).

For each of the process/apparatus restrictions between Inventions V and I; VI and I; II and V; and II and III; the Office Action states that “[i]n this case the method performed by the implantable device required by [the particular method invention] could be practiced by leadless or external electrodes, rather than by the implantable, leaded electrodes required by [the particular apparatus invention].”

The Applicant respectfully submits that because each method invention recites some variation of an implantable device performing a monitoring step, among other steps, doing the same with external electrodes is not a reasonable example to show a material difference.

Furthermore, the Applicant respectfully submits that the Examiner has failed to provide a reason why performing the methods with leadless electrodes is materially different than doing the same with electrodes on leads, particularly in the context of the Applicant’s claims. The Examiner does not explain why the leadless embodiment is materially different or that the absence of leads is of any consequence in the context of the Applicant’s claims.

Also, it is noted that in the above discussion, as elsewhere in this restriction response, the Applicant is only addressing the Office Action’s failure to meet the requisite burden for sustaining a restriction, and is not characterizing the claims, the claimed invention, any prior art, or the patentability of the claims.

Therefore, the Examiner has failed to meet the requisite burden to establish that Inventions V and I; VI and I; II and V; and II and III, are materially different and properly restrictable. (MPEP 806.05(e)). For at least these reasons, the Applicant respectfully requests withdrawal of the restriction between Inventions V and I; VI and I; II and V; and II and III.

Restriction between inventions related as a process and apparatus requires that “the apparatus *as claimed* can be used to practice another materially different process.” (806.05(e)(B); emphasis original).

For each of the process/apparatus restrictions between Inventions IV and V; and IV and VI; the Office Action states that “the apparatus claimed by [the particular apparatus invention] could be used to provide external storage of cardiac signals for review by a physician that is remote from the patient.” (Office Action, Pages 7-8).

The Applicant respectfully submits that even if the respective apparatuses could be used to provide external storage, this is merely an additional feature and does not provide for a materially different process. For example, remote storage of cardiac signals for review by a physician could be practiced in addition to the process Inventions. Accordingly, merely adding external storage does not materially change the process, as the process is still the same process. The Examiner does not explain why the addition of an external storage step with the hypothetical process for use of the respective apparatuses is a materially different process. It appears that they could still basically be the same processes, only with one having a further external storage step.

Therefore, the Examiner has failed to meet the requisite burden to establish that Inventions IV and V; and IV and VI are materially different and properly restrictable. (MPEP 806.05(e)). For at least these reasons, the Applicant respectfully requests withdrawal of the restriction between Inventions IV and V; and IV and VI.

Restriction between inventions related as subcombinations requires that “the subcombination can be shown to have utility either by itself or in another materially different combination.” (MPEP § 806.05(d)(B)).

In support of the restriction between inventions II and III, the Examiner states that Invention II has separate utility such as a patient controlled method of operating the implantable device, specifically by actuating a switch. The Applicant respectfully submits

that the actuatable switch is part of a patient implantable cardiac device, according to claim 23. Therefore, the implanted switch is not patient actuatable, as contended by the Examiner.

Accordingly, the Applicant respectfully submits that the Examiner has not provided a separate utility and therefore has failed to meet the necessary burden to properly support the restriction requirement between Inventions II and III. (MPEP § 806.05(d)(B)).

In order to establish reasons for insisting upon restriction, the Examiner must explain why there would be a serious burden on the Examiner if restriction is not required. (See, MPEP § 808.01(a) which references MPEP § 808.02). To comply with this requirement, the Examiner must show by appropriate explanation one of the following (1) separate classification; (2) separate status in the art when they are classifiable together, or (3) a different field of search. (MPEP § 808.02; see also MPEP § 806.05(d)(B)).

The Examiner states that the inventions “have acquired a separate status in the art due to their recognized divergent subject matter.” (Office Action, Page 10). Section 808.02(b) of the MPEP, under the heading “Establishing Burden,” states that separate status in the art is established when “each invention can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.” (Emphasis added).

The Applicant respectfully submits that the Examiner has failed to meet the requisite burden and only provides a conclusory statement asserting that the inventions have separate status in the art. The Examiner does not provide any evidence, by way of patents or otherwise, showing a recognition of separate inventive effort by inventors, as explicitly required by MPEP § 808.02(b). The Examiner must withdraw the restriction between Inventions I-VII if the Examiner refrains from providing the necessary showing for establishing the existence of a serious burden under MPEP § 808.02. (see also MPEP § 806.05(d)(B)).

For at least all of the reasons discussed above, the Applicant respectfully submits that the Examiner is compelled to withdraw each respective restriction requirement between each of Inventions I, II, III, IV, V, VI, and VII.

The discussion contained herein is not to be construed as containing an admission or characterization on the part of the Applicant. The discussion of this restriction response is only addressing the Office Action's failure to meet the requisite burden for sustaining a restriction, and is not characterizing the claims, the claimed invention, any prior art, or the patentability of the claims.

CONCLUSION

In view of the above, the Applicant respectfully requests reconsideration and withdrawal of the requirement for restriction. If the Examiner would find it helpful to discuss this issue by telephone, the undersigned attorney of record invites the Examiner to contact the attorney of record.

Respectfully submitted,

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